



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/084,837	05/26/98	LUTICKEN	H 1/97269-US

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HM21/0908

EXAMINER

MOSHER, M

ART UNIT

PAPER NUMBER

1643

DATE MAILED:

09/08/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/084,837

Applicant(s)
Lutticken et al

Examiner
Mary Mosher

Group Art Unit
1643



☒ Responsive to communication(s) filed on 5/26/97

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10, 12, 13, and 15-31 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4, 10, 12, 13, 15-22, 24, 26, 28, 29, and 31 is/are rejected.

☒ Claim(s) 5-9, 23, 25, 27, and 30 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

X Sequence Notice, error report

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

The Sequence Listing filed 5/26/98 does not comply with the Sequence rules for the reason(s) set forth on the attached Error Report. Correction is required.

Claim Rejections - 35 USC § 112

Claims 1-4, 10, 22, 24, 26, 28 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the full scope of the claimed invention. There are two different facets to this rejection, one involving the scope of "birnavirus" and one involving the scope of "a substitution" which makes the virus "not able to produce a native VP5 protein". In the first case, the specification teaches one to produce the mutant virus by recombinant manipulation of the genome. In order to make the claimed viruses, one is therefore required to possess DNA clone(s) which produce full-size, infectious genomic RNA for each of the birnaviruses. The only such DNA clones set forth in the specification are clones of IBDV. Since the specification provides only a single species within the scope of the claimed birnaviruses, and it does not appear that the necessary DNAs for other birnaviruses are in the possession of applicants or of the general public, it is concluded that the specification does not adequately describe or enable the full scope of the claimed birnaviruses. In the second case, claim 2 (and dependent claims 22, 24, 26, 28, and 31) requires possession of all of the possible sequences of "a native VP5 protein" in order to possess substitution mutations which produce something other than "a native VP5 protein". Since the

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specification and the prior art do not describe all of the variations possible in native VP5 sequences, it appears that applicant was not in possession of the full scope of substitution mutations claimed. For these reasons, the specification is seen as limited to an adequate written description of mutant IBDV, and to mutations which delete VP5 sequence, insert heterologous sequence, or substitute heterologous sequence for VP5.

Claims 1-4, 10, 22, 24, 26, and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for mutant IBDV, and to mutations which delete VP5 sequence, insert heterologous sequence, or substitute heterologous sequence for VP5, does not reasonably provide enablement for the full scope of birnaviruses claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is made for essentially the same reasons as the "written description" rejection above.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for IBDV vaccines, does not reasonably provide enablement for the full scope of birnavirus vaccines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. As discussed above, the specification adequately describes only the IBDV species of birnavirus, when describing materials which are essential to make the claimed invention. In addition, these claims involve vaccines with VP5 mutant birnavirus. Applicant has observed attenuation using VP5 mutant IBDV, but others have not correlated the absence of VP5

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to attenuation in other birnaviruses, see for example Heppell et al. Since attenuation and vaccine efficacy are unpredictable, one skilled in the art would have reason to doubt that the observations based on IBDV would necessarily predict results in very different hosts (chickens versus fish, for example). For these reasons, enablement is seen as limited to use of IBDV.

Claims 15, 28, 29, and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that the DNA encoding the genome of IBDV strain D78 is required to practice the claimed invention, since these claims are drawn to mutants made from this strain. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit. It is noted that the necessary starting materials have been described in a printed publication, but it is not clear that the necessary materials are publicly available. The specification does not provide a repeatable method for obtaining the D78 genome. Deposit of clones encoding the A and B segments of D78 would satisfy the enablement requirements of 35 U.S.C. 112.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be

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irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 12, 13, 16-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Heppell et al.

Allowable Subject Matter

Claims 5-9, 23, 25, 27, and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of

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the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196 .

September 7, 1998


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1643
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